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FORUM
risk frameworks and biomonitoring:
DISTRIBUTED REGULATION OF SYNTHETIC CHEMICALS IN HUMANS

ENVISION BRIEFLY TWO hypothetical individuals. The first is a chemical engineer who works directly in the synthesis of compounds added to plastics to give them desired properties such as flexibility and hardness. By some analyses, this person has taken on voluntary risks related to the workplace; furthermore this person is protected by federal and state regulations governing chemical exposure and worker safety.[1] The second is a vegan environmentalist who works in a natural foods store and enjoys hiking in national parks. This person makes lifestyle choices to avoid exposure to synthetic chemicals and may reasonably assume that federal laws regulating the introduction of new chemicals ensure safety under normal conditions. Yet when their blood is tested, they have similar levels—measured at parts per billion—of compounds known to cause harm at much higher doses. How should they interpret this finding? Is it possible that people with such different exposure to chemicals have similar "body burdens"?[2] Because of the minute quantities of materials that all of us absorb through regular encounters with synthetics, this scenario of equivalent measures in two otherwise different people can occur. Whether drinking from plastic bottles while enjoying remote vistas, working at a chemical plant, or engaged in one of thousands of routine daily activities, we are exposed to trace amounts of industrial compounds that make their way into our bodies and environmental systems.

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Over the past century, and at an accelerated rate in recent years, new analytical tools have made it possible to identify substances at a part per million, billion, or even trillion (the equivalent of finding a single grain of sand in an Olympic-sized swimming pool). In the United States, the Centers for Disease Control and Prevention (CDC) now regularly survey the population for the presence of 275 specific chemicals. In addition to the CDC surveys, biomonitoring studies carried out by academic scientists and by a variety of environmental NGOs are generating significant new data about the presence of chemicals in the U.S. population and eventually will measure changes in chemical presence over time. These efforts to measure and track chemicals pose a complex challenge to a regulatory system that historically was focused on controlling the physical location of hazardous compounds and measured risk based on a calculus of hazard and exposure.[3]

This essay argues that new technologies for measuring synthetic chemicals in humans, innovations in the field of toxicology, and increased mobilization by environmental nongovernment organizations (NGOs) regarding chemical exposure are combining to undermine risk frameworks and regulatory systems built up over the past quarter-century. In effect, the very definition of risk used in regulatory decisions is at play as a result of biomonitoring's emerging measures of chemicals in bodies at parts per billion or below. I argue that a two-part shift is underway associated with biomonitoring: first, from regulating chemicals by physical location to regulating them by chemical reaction; second, from defining risk as a function of exposure to chemicals to basing it on the presence of compounds in the body. Regulating chemicals by location relied on clear delineations between industry and government, with central control and oversight by federal agencies producing visible environmental and human health benefits. Regulating chemicals by reaction will involve distributed controls and require greater cooperation among interested parties to define standards, carry out biomonitoring, and make policy decisions that draw on test results. Drawing on the historical trajectory of changing regulatory methods, this essay advances a regulatory framework that involves collaborative testing programs and information sharing among industry, NGOs, and government agencies.

REGULATION BY LOCATION

EVER SINCE THE CHEMICAL INDUSTRY'S origins in mining and extraction, though with greater intensity once synthetic dyes fostered international growth in the late nineteenth century, efforts at controlling human and environmental exposure have focused on location. Materials in the wrong place, such as leftovers from potash and soda manufacture or synthetic dyes coloring rivers purple were considered pollutants. Materials in the right place were productive elements of an industrial age that promised greater prosperity and quality of life.[4]

As the first legal and regulatory interventions emerged to control the disposal of byproducts of manufacturing, physical location proved critical. Over the course of the latter third of the twentieth century, the EPA, industry, and academic scientists developed sophisticated models for how pollutants travel in air and water or migrate through soil. Disputes, such as over the Love Canal disaster,

have hinged in part on testing for the physical presence of hazardous compounds. Resolution in cases of accidental releases or discovery of buried toxins involved moving people or physically removing the pollutant, frequently at high costs.[5]

Beginning in the 1960s, however, a combination of new laboratory and field studies shifted attention to the finding that chemicals in the environment could harm wildlife and cause cancer in humans.[6] Much of the subsequent political mobilization around carcinogens sought to develop control measures on pollution, whether from a smokestack or a waste stream. Some studies also began tracking human health effects of chemicals found in consumer products and packaging, including studies of toxicity an carcinogenicity.

The central legislative act for regulating chemical safety in the United States, the Toxic Substances Control Act (TSCA), was passed by Congress in 1976. Written at a time of concern with cancer and its relationship to environmental factors, the legislation listed and banned known or suspected carcinogens, including vinyl chloride, asbestos, and PCBs.[7] Unlike other federal environmental regulatory statutes, such as the Clean Air Act or Clean Water Act, TSCA required manufacturers to characterize the risks posed by new chemicals before they could be introduced to commerce. As implemented, this provision required firms to submit a pre-manufacture notification (PMN) ninety days before producing or importing a new chemical substance. Yet in the period between 1979 and 2002, some two-thirds of PMNs filed with the agency failed to provide complete data on physical properties or environmental impacts. As a result, the agency largely regulated compounds based on structure-activity relationships in which potential effects of a new chemical are estimated based on the known characteristics and effects of structurally similar molecules. More recently, voluntary initiatives such as the high production volume testing program have begun to fill in gaps for basic information on chemicals in commerce.[8]

TSCA's sections concerning the regulation of existing chemicals called for the EPA to balance the economic and social benefits derived from the use of a chemical against its risks. The agency was to regulate those chemicals that presented an "unreasonable" risk of harm to human health or the environment.[9] Since Congress did not specifically define "unreasonable" risk, the agency found itself caught in extensive and costly cycles of litigation and delay as environmental groups and manufacturers interpreted the benefit-risk balance differently. Since 1976, only six existing substances or chemical groups have been banned. Other substances in widespread commercial use for decades, including phthalates, bisphenol-A, and brominated fire retardants remain embroiled in disputes over exposure, effects on humans and wildlife, and the economic consequences of regulation.[10]

Facing a multidecade dilemma of both incomplete data on synthetic materials and scientific uncertainty about how to design risk assessments that did not "unreasonably" take chemicals out of commerce, EPA's regulatory approach became dominated by exposure assessment. Officials focused on manufacturing sites, transportation pathways, and (less frequently) people living in close proximity to manufacturers. The combination of occupational health and safety

laws with TSCA meant that most monitoring for health impacts from exposure was carried out on plant workers. As Michael Egan points out elsewhere in this forum (pp. 636-642), once compounds are in the environment and interact with biological systems, tracing their origins can become nearly impossible.

Identifying hazards through place-based analysis and regulating pollution through end-of-pipe controls are fundamentally linked to defining risk as hazard times exposure (see Sarah Vogel's essay, pp. 667-673 in this forum, for more on the development of the formula, risk = hazard x exposure). With the hazards posed by pollution often visible or odorous, wealthier people physically separated themselves from manufacturing sites.[11] A prevailing assumption, seemingly borne out by public health surveys, was that avoiding direct contact with pollutants would reduce cancer rates and extend healthy lifespan. Under this regulatory framework, government agencies regulated "point-sources" of pollution and forced environmental cleanups in order to ensure safe physical locations for humans and wildlife.

REGULATION BY CHEMICAL REACTION

THE PROLIFERATION OF BIOMONITORING studies since the early-1990s is challenging key aspects of prevailing methods for calculating risk and controlling chemicals. Two kinds of studies have emerged in recent years, with broad surveys by the government tracking chemicals across the entire population and narrower studies by academics and NGOs focusing on specific compounds or subpopulations.[12] Together, these tests are indicative of a shift underway from pollution in air, water, or soil to measuring chemicals in bodies. They also suggest that regulatory systems based on central government control over the location of chemicals will need reform to achieve human and environmental health goals based on interactions among chemicals and body systems.

The origins of what today has become known as biomonitoring can be dated back to public health studies of lead levels among inhabitants of Baltimore, Boston, and other northeast cities starting in the 1890s.[13] During the following century, testing people's blood, teeth, tissue, or fat for the presence of specific compounds was undertaken in an episodic manner. Nevertheless, biomonitoring studies affected policy debates in areas as diverse as nuclear testing and worker safety.

In the late 1950s, Barry Commoner and the Committee for Nuclear Information initiated a study that eventually collected over 60,000 children's teeth and measured strontium-90 absorption. Results suggested that background levels of the radioactive material had increased one-hundred-fold after 1948, providing a powerful rationale for the ban on atmospheric nuclear weapons testing passed in 1963.[14]

In a second example, the publication of studies linking vinyl chloride (a precursor to PVC) to cancer in laboratory animals and identification of VC-related cancers in employees at a B.F. Goodrich plant in Louisville sparked a controversy regarding the compound in the early 1970s.[15] In the wake of a contentious exposure

standard-setting process by the Occupational Safety and Health Administration (OSHA), firms began to closely monitor workers exposed to vinyl chloride and other compounds by collecting urine and blood samples.

As a result of these and other controversies, government agencies ranging from the Nuclear Regulatory Commission to OSHA became aware of new analytical techniques for identifying chemicals in humans. In the mid-1990s,the CDC began to include data on lead and compounds found in cigarette smoke in the National Health and Nutrition Examination Survey (NHANES) it had administered since 1971. After 2001, the CDC NHANES report incorporated biomonitoring studies, initially measuring twenty-seven chemicals.[16] Phthalates–compounds that act as plasticizers in many consumer products–were found at unexpectedly high levels and sparked interest among NGOs in the United States and Europe. Media reports soon drew attention to the fact that we all contain these chemicals.[17]

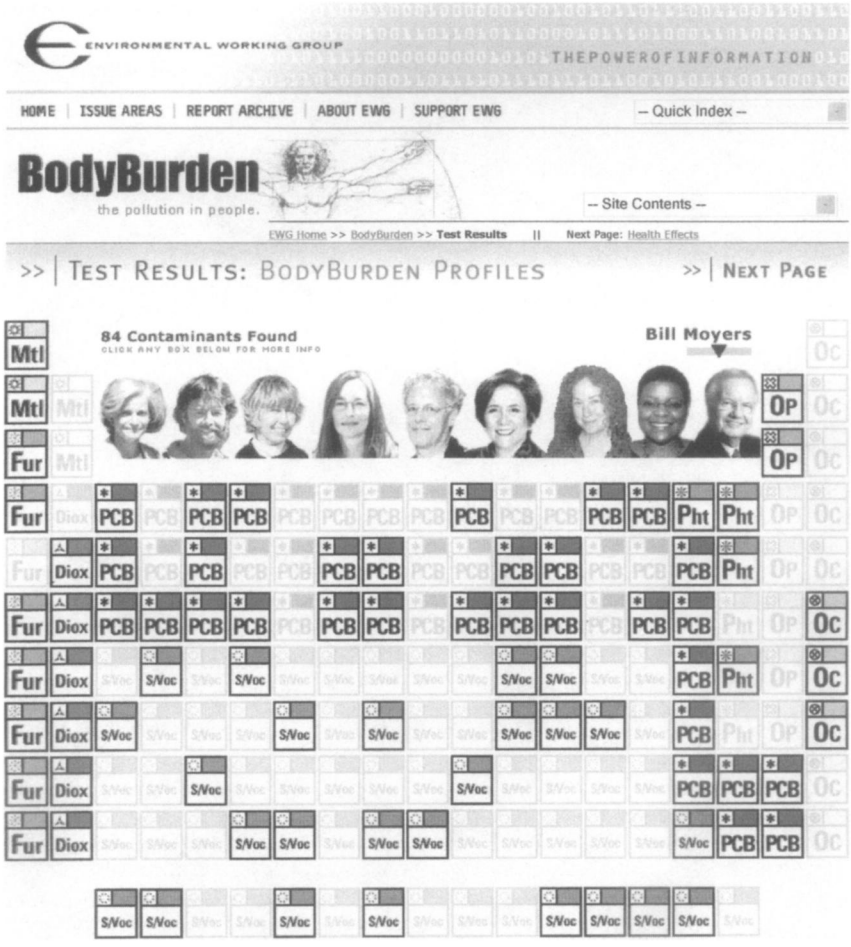
CDC released a second *National Report on Human Exposure to Environmental Chemicals*, in February 2004.[18] Covering 116 chemicals measured in blood and urine from a sample of 3,500 people, the survey targeted a number of specific populations, including African-Americans, whites of lower economic class, pregnant women, and people over 60 years old. These populations were chosen partly in response to concerns expressed by environmentalists and public health experts that data available to EPA rarely includes populations other than plant workers. Likewise, CDC's selection of chemicals to monitor was based on several criteria, including suspected health consequences of exposure and direct lobbying by environmentalists and public health experts.

The 2005 CDC report covered 148 chemicals based on a sample of 2,400 people from across the United States.[19] The data showed both encouraging and potentially alarming trends. Among the former, the pesticides aldrin, endrin, and dieldrin were undetected or only present at very low levels and the percentage of children with elevated blood lead levels declined significantly from previous surveys. Phthalates were measured with greater sensitivity, though CDC noted that there is little basis yet to judge health effects at the detected levels, stating "just because people have an environmental chemical in their blood or urine does not mean that the chemical causes disease."[20] Other compounds present in people included polycyclic aromatic hydrocarbons and a variety of dioxins and furans. A fourth national report scheduled for release in late 2008 will cover 275 chemicals; CDC also has begun issuing interim reports on specific compounds.

Largely independent of government-sponsored surveys, NGOs and academic centers have collected data on synthetic chemicals in humans through their own biomonitoring studies. Sampled populations and reporting styles have varied considerably, ranging from politicians to babies, and from peer-reviewed publication to interactive websites. A common thread to the NGO studies is the goal of using results as the basis for mobilizing public concern and political action.

In perhaps the best-known series of nongovernmental biomonitoring surveys, the Environmental Working Group (EWG) began to test adults and children for

Figure 1. Body Burden Profile.



The EWG "Body Burden" website visually portrayed testing results for a small group of people in a style similar to the periodic table of the elements. This image features chemicals found in Bill Moyers, a journalist, commentator, and critic of the chemical industry.

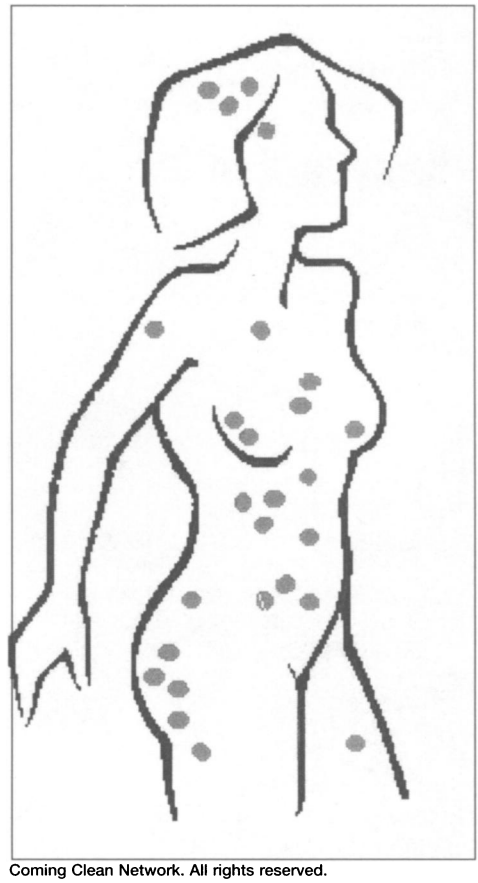
the presence of synthetic chemicals in 2002. An initial study carried out with Mount Sinai School of Medicine included twelve well-known scientists and media personalities. EWG found an average of 91 industrial compounds in each person, with a total of 167 different chemicals across the group. Results were then displayed on the web in an interactive format reminiscent of the periodic table showing the variants of PCBs, furans, and other organic compounds in each participant's blood.[21] More recently, EWG shifted attention to infants as an at-risk population with a study measuring the transfer of industrial chemicals from mothers to their daughters through the placenta or breast milk. Concerned that "a substantial portion of the chemical burden inherited at birth by the daughters in this study will last for decades; some will last a lifetime," EWG recommended

that consumers should avoid food, packaging, and household items containing six specific compounds, ranging from lead to brominated flame retardants.[22]

Similarly, the World Wide Fund for Nature tested blood samples from 156 Europeans in 2003, including fourteen ministers of health and environment. Findings showed that all participants contained polychlorinated biphenyls, organochlorine pesticides, and other compounds. Results were published in a report titled "Bad Blood."[23] Reporting the results, Dr. Vyvyan Howard of the University of Liverpool stated, "exposure is universal."[24]

A second type of NGO study more explicitly seeks to promote an environment free from chemical exposure. For example, the "Coming Clean Network" website shifts the reader's attention from well-known cancer sites such as a woman's breast to risks posed by chemicals located elsewhere in the body. The organization presents case studies of ex-posure and makes suggestions for how to avoid contact with toxins.[25] Likewise, a 2004 report by the Pesticide Action Network (PAN) featured cover imagery of children at play and a mother and child facing the threat of unwelcome chemical exposure from industrialized agriculture.[26]

Figure 2. Coming Clean.



The Coming Clean Network's portrayal of a body at risk suggests that potential toxins are distributed widely, not just concentrated in one place.

Third, a number of interactive websites give estimates of people's exposure to synthetic chemicals and their consequent "body burden" based on questions about lifestyle, including the use of cosmetics and cleaning agents.[27] Combining play with education, the World Wildlife Fund hosts an asteroids-type video game called "Toxic Blaster" in which visitors pilot a spaceship that shoots toxins, first in a polar bear, then a whale, and ultimately in a human. Screens pop up between levels that invite participants to "take action now" by learning more about chemicals and by contacting congressional representatives.[28]

Unlike the CDC's population survey and high level of data aggregation, NGO-

Figure 3. Toxic Blaster.

The toxic blaster site seeks to use a video game to mobilize political action regarding chemicals in wildlife and humans.

sponsored studies personalize biomonitoring data and couple results to suggestions for how individuals can take action in the absence of government regulation of compounds such as phthalates, bisphenol-A, and others. In a recent example of their influence, Nalgene, the manufacturer of polycarbonate drinking bottles popular with outdoor enthusiasts, announced the phase-out of bisphenol-A, while expert commissions and regulators in the United States, Canada, and European Union came to different conclusions about designating it a toxic substance.[29]

Many of the biomonitoring studies are not comparable, making it difficult to analyze a specific chemical across different tests. Likewise, at present no coordinated priority-setting is taking place among the groups carrying out studies to select among the 15,000 chemicals in commerce or the 80,000 chemical substances listed on the EPA's complete inventory. Diverse national surveys, population surveys, studies of specific sub-populations, and even tests of small influential groups pose a significant challenge to traditional regulatory analysis.

As biomonitoring expands its reach, it will impact the risk calculus employed in regulatory decision-making. From measuring risk as a product of hazard and exposure, risk is shifting to be defined as hazard times the amount of a compound measured in the body. Theoretically, large-scale testing programs underway to collect and publish hazard data on chemicals in commerce could be coupled to biomonitoring results to give far more detailed risk measures than were previously possible. This will require both additional testing and a more distributed and coordinated regulatory approach.

DEMOCRATIZING RISK

ADVANCES IN ANALYTICAL CHEMISTRY, increased mobilization by environmental NGOs, and the emergence of biomonitoring studies are contributing to an emerging form of risk democratization. As we learn about the ways in which trace amounts of chemicals enter our bodies, wealthier people no longer escape exposure as they hoped to in the past by moving to less industrialized landscapes. While workers in developing countries who disassemble discarded electronics clearly are exposed to more flame retardants and heavy metals than those who use computers in office buildings, there are no obvious routes to avoid any measurable exposure. Biomonitoring thus challenges the concept that specific, identifiable, and manageable parts of technical, engineering, and industrial systems are the key loci of risk. Now consumer culture itself acts as an exposure pathway and risk conduit (a concept developed further in Michelle Murphy's essay in this volume).

We live in an era in which consumer products, electronic devices, food packaging, and building materials are manufactured by the chemical industry. NGOs have endeavored in recent years to make the underlying substances, supply chains, and exposure pathways more visible to the public, in part through biomonitoring studies. For regulators, this information poses challenges to ways of calculating risk and ensuring the safety of chemicals.

At the same time, over the last two decades command-and-control regulation reached its political limits and deregulatory initiatives were advanced in the United States. For a variety of testing initiatives and reporting programs, ranging from high-production volume chemicals to the toxic release inventory, the EPA acts less like a traditional regulator than as a forum hosting results that are then debated and used by industry and NGOs. Effective regulation based on biomonitoring studies will require industry, NGOs, and the EPA to resolve what will count as appropriate tests in this area. Currently we are relying—for better or worse—on industry to self-regulate under watchful and critical NGO observation.

Biomonitoring would benefit from a central data depository that would standardize and electronically post results. In this new regulatory model, the EPA would host data and ensure that test results meet basic standards. Unlike the current division among agencies or divisions responsible for insecticides, food packaging, cosmetics, and other products, a central biomonitoring data set is needed to make meaningful comparisons, measure risk levels, and understand exposure pathways. The initial data set could be built out of CDC and other national surveys, but to be effective and inclusive, results from industry studies and NGO surveys of targeted communities should also be included. Over time it would become clear whether levels are declining or increasing, epidemiologists and other public health scientists could draw on the data sets for research, and the public could view results in a single location.

The social and political roles of government, citizen groups, and industry shifted significantly over the past three decades. Government agencies used to issue standards and rules; now they sometimes coordinate voluntary testing programs. NGOs used to ask the government to regulate more; now they directly

negotiate with or confront the private sector, often with extensive scientific data in hand.[30] In the case of toxics release inventories, they largely rely on firms to supply data to EPA. In biomonitoring studies, NGOs play an active role in developing the data. Citizens used to assume certain relationships with the government and industry, but consumers have a status based more on financial power than voting. Corporations have taken on certain attributes previously thought to belong to nation-states, but have not felt compelled to institute structured forms of representation beyond shareholder (proxy) voting. Resolving these dilemmas and stabilizing the shifting roles of industry, government, and NGOs are critical to the future of chemicals regulation.

A distributed system for testing and hosting data holds the potential for greater transparency and improved availability of information about chemicals in consumer products than has been possible under classic regulatory structures. This neoliberal model should not preclude the possibility of more traditional rule-making or standard-setting in cases where concerns emerge under the new risk model. But it does offer a means to overcome stasis in an area of high uncertainty like biomonitoring at present.

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NOTES

1. Chauncey Starr, "Social Benefit versus Technological Risk: What is Our Society Willing to Pay for Safety?" *Science* 165 (1969): 1232-38; Baruch Fischoff et al., "How Safe is Safe Enough? A Psychometric Study of Attitudes toward Technological Risks and Benefits," *Policy Sciences* 9 (1978): 127-52.
2. Environmental NGOs popularized the term "body burden" to signal a total synthetic chemical load borne by humans. See: www.chemicalbodyburden.org.
3. Scholars have long noted the influence of values, ethics, and political culture on regulatory definitions of risk. See: Mary Douglas and Aaron Wildavsky, *Risk and Culture: An Essay on the Selection of Technological and Environmental Dangers* (Berkeley and Los Angeles: University of California Press, 1982); Ronald Brickman et al., *Controlling Chemicals: The Politics of Regulation in Europe and the United States* (Ithaca, NY: Cornell University Press, 1985), 187-217; Sheila Jasanoff, *Risk Management and Political Culture* (New York: Russell Sage Foundation, 1986), 25-32, 69-77.
4. John K. Smith, "Turning Silk Purses into Sows' Ears: Environmental History and the Chemical Industry," *Enterprise and Society* 1 (2000): 785-812.
5. Adeline Levine, *Love Canal: Science, Politics, and People* (Lexington, MA: Lexington Books, 1982); Marc Landy et al., *The Environmental Protection Agency: Asking the Wrong Questions* (New York: Oxford University Press, 1990).
6. Rachel Carson, *Silent Spring* (Boston: Houghton Mifflin, 1962), 15-51.
7. H.R. Rep. No. 94-1241, at 4.
8. www.epa.gov/hpv/index.htm.
9. Library of Congress, Environment and Natural Resources Policy Division, *Legislative*

History of the Toxic Substances Control Act (Washington, DC: U.S. Government Printing Office, 1976).

10. McKenna Long & Aldridge LLP, *TSCA Handbook*, 4th Ed. (Lanham, MD: Scarecrow Press, 2005), 7-12; Theo Colborn et al., *Our Stolen Future* (New York: Penguin, 1997), 210-30.
11. This issue came to the fore in the environmental justice movement of the 1990s: see Phil Brown, *Toxic Exposures: Contested Illnesses and the Environmental Health Movement* (New York: Columbia University Press, 2007); and Robert Bullard, *Dumping in Dixie: Race, Class, and Environmental Quality* (Boulder, CO: Westview Press, 1990).
12. Ken Sexton et al., "Human Biomonitoring of Environmental Chemicals," *American Scientist* 92 (2004): 38-45; Alastair Iles, "Identifying Environmental Health Risks in Consumer Products: Non-Governmental Organizations and Civic Epistemology," *Public Understanding of Science* 16 (2007): 371-91.
13. Christian Warren, *Brush With Death: A Social History of Lead Poisoning* (Baltimore: Johns Hopkins University Press, 2000); Gerald Markovitz and David Rosner, *Deceit and Denial: The Deadly Politics of Industrial Pollution* (Berkeley: University of California Press, 2002).
14. Michael Egan, *Barry Commoner and the Science of Survival* (Cambridge: MIT Press, 2007).
15. Joseph Badaracco, *Loading the Dice: A Five-Country Study of Vinyl Chloride Regulation* (Boston: HBS Press, 1985), 5-18.
16. Centers for Disease Control and Prevention, *First National Report on Human Exposure to Environmental Chemicals* (Atlanta: CDC, 2001).
17. For representative examples, see Peter Waldman, "Common Industrial Chemicals in Tiny Doses Raise Health Issue," *Wall Street Journal* (25 July 2005): A1, A12; and David Duncan, "Pollution Within," *National Geographic* (October 2006): 116-43.
18. Centers for Disease Control and Prevention, *Second National Report on Human Exposure to Environmental Chemicals* (Atlanta: CDC, 2004).
19. Centers for Disease Control and Prevention, *Third National Report on Human Exposure to Environmental Chemicals*. (Atlanta: CDC, 2005).
20. CDC, *Third National Report*, Executive Summary, 2.
21. The site subsequently was taken down, although the EWG has extensive information at www.ewg.org/sites/humantoxome.
22. Environmental Working Group, "Across Generations" (May 10, 2006), 2. See also Jane Houlihan et al., *BodyBurden: The Pollution in Newborns* (Washington, DC: EWG, 2005).
23. World Wildlife Fund, *Bad Blood? A Survey of Chemicals in the Blood of European Ministers* (Brussels: WWF, 2004).
24. "EU Citizens are Walking Chemical Cocktails," EUobserver.com (August 6, 2003).
25. See: www.chemicalbodyburden.org.
26. Kristin Schafer et al., *Chemical Trespass: Chemicals in Our Bodies and Corporate Responsibility* (San Francisco: Pesticide Action Network, 2004).
27. See: Inside Bay Area, "A Body's Burden: Our Chemical Legacy," extras.insidebayarea.com/bodyburden/bodyburden.html.
28. http://assets.panda.org/custom/games/toxicblaster.
29. Ian Austen, "Bottle Maker to Stop Using Plastic Linked to Health Concerns," *New York Times* online (18 April 2008).
30. Sheila Jasanoff, "NGOs and the Environment: From Knowledge to Action," *Third World Quarterly* 18 (1997): 579-94; Debora Spar, and Lane LaMure, "The Power of Activism: Assessing the Impact of NGOs on Global Business," *California Management Review* 45 (2003): 78-101.